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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,760	06/22/2000	Martha K. Newell	10277/7009 HCL	8006

7590

04/23/2002

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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/23/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,760

Applicant(s)

NEWELL, MARTHA K.

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-64 and 66-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 60-64 and 66-72 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This Office action is in response to the communication filed February 7, 2002, Paper No. 12.

Priority

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Election/Restriction

This application contains claims 1-59, 65, 73 and 74, drawn to inventions nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Response to Arguments and Amendments

Withdrawn Rejections

Rejection of claims 64 and 67 under 35 U.S.C. 112, second paragraph, is withdrawn in light of Applicants' amendments and remarks filed February 7, 2002, Paper No. 12.

Maintained Rejections

Claims 60-64 and 66-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the previous Office action mailed July 12, 2001, Paper No. 11.

Applicant's arguments filed February 7, 2002 have been fully considered but they are not persuasive. Applicants argue that the discovery revealed in the instant disclosure that UCP is expressed in the lysosomes, combined with the findings of Arsenijevic et al, that UCP2 knockout in mice increased the ability to resist and eliminate infections enables the claimed invention, drawn to methods of regulating lysosomal pH, as well as treating and preventing infectious diseases comprising the administration of any lysosomal UCP inhibitor. Contrary to Applicants' assertions, no regulation of lysosomal pH has been demonstrated using any UCP inhibitors, nor has the prevention or treatment of infectious diseases been shown in an organism comprising the administration of any UCP inhibitors. The specification teaches the subcellular localization of UCP to be in the lysosomes of rapidly dividing, drug sensitive cells. The specification also

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teaches the shift in UCP subcellular localization (upon inhibition of N-glycosylation by tunicamycin treatment) from lysosomes and mitochondria to the plasma membrane in vitro.

These teachings are not correlative or representative of the ability to regulate lysosomal pH in a predictable manner using any and/or all UCP inhibitors, nor is it correlative or representative of the ability to prevent or treat any and/or all infectious diseases in an organism comprising the administration of any and/or all UCP inhibitors.

Applicants argue that a reasonable inference from the data provided by Arsenijevic et al, combined with the data provided in the instant disclosure regarding UCP expression in the lysosomes, is that the loss of lysosomal UCP expression is associated with an ability to treat and/or prevent infections in an organism, or that the regulation of lysosomal pH is believed to be associated with the ability to prevent and/or treat infectious diseases. It is unclear without correlative data that lysosomal pH is predictably regulated using any and/or all UCP inhibitors, including such agents as the glycosylation inhibitor tunicamycin, which inhibits all N-linked glycosylation, and not just that of UCP. The regulation of lysosomal pH using any and/or all inhibitors of UCP is highly unpredictable in vitro or in vivo. It would require undue experimentation beyond that which has been taught in the prior art or in the instant specification for enabling the claimed invention, drawn to methods of predictably regulating lysosomal pH using any lysosomal UCP inhibitor, and further where disease prevention and treatment effects have been provided.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'SEAN MCGARRY', with a long horizontal flourish extending to the right.

**SEAN MCGARRY
PRIMARY EXAMINER**

JZ

April 22, 2002